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<b>UTILITY PATENT APPLICATION TRANSMITTAL</b>  <small>(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))</small>	Attorney Docket No.	30111-pa
	First Inventor or Application Identifier	Coelho, et al.
	Title	Freezing and Thawing Bag, Mold ...
	Express Mail Label No.	EK241513481US

<b>APPLICATION ELEMENTS</b> <small>See MPEP chapter 600 concerning utility patent application contents.</small>	<b>ADDRESS TO:</b> Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
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- ☒ \* Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
- ☒ Specification [Total Pages 19]  
(preferred arrangement set forth below)
  - Descriptive title of the invention
  - Cross References to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to Microfiche Appendix
  - Background of the invention
  - Brief Summary of the invention
  - Brief Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
- ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 10]
- Oath or Declaration [Total Pages]
  - ☐ Newly executed (original or copy)
  - ☒ Copy from a prior application (37 C.F.R. § 1.63(d))  
(for continuation/divisional with Box 16 completed)
    - ☐ **DELETION OF INVENTOR(S)**  
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

- ☐ Microfiche Computer Program (Appendix)
- Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)
  - ☐ Computer Readable Copy
  - ☐ Paper Copy (identical to computer copy)
  - ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS	
7. <input type="checkbox"/>	Assignment Papers (cover sheet & document(s))
8. <input type="checkbox"/>	37 C.F.R. § 3.73(b) Statement <input type="checkbox"/> Power of Attorney <small>(when there is an assignee)</small>
9. <input type="checkbox"/>	English Translation Document (if applicable)
10. <input checked="" type="checkbox"/>	Information Disclosure Statement (IDS)/PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations
11. <input checked="" type="checkbox"/>	Preliminary Amendment
12. <input checked="" type="checkbox"/>	Return Receipt Postcard (MPEP 503) <small>(Should be specifically itemized)</small>
13. <input checked="" type="checkbox"/>	* Small Entity Statement(s) <input checked="" type="checkbox"/> Statement filed in prior application, Status still proper and desired <small>(PTO/SB/09-12)</small>
14. <input type="checkbox"/>	Certified Copy of Priority Document(s) <small>(if foreign priority is claimed)</small>
15. <input type="checkbox"/>	Other: _____

**\* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).**

16. If a **CONTINUING APPLICATION**, check appropriate box, and supply the requisite information below and in a preliminary amendment:

☐ Continuation ☒ Divisional ☐ Continuation-in-part (CIP) of prior application No: 08, 978,171

Prior application Information: Examiner Olsen, K. Group / Art Unit: 1744

**For CONTINUATION or DIVISIONAL APPS only:** The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. **CORRESPONDENCE ADDRESS**

☐ Customer Number or Bar Code Label or ☒ Correspondence address below

(Insert Customer No. or Attach bar code label here)

Name	Bernhard Kreten				
Address	77 Cadillac Drive, Suite 245				
City	Sacramento	State	CA	Zip Code	95825
Country	US	Telephone	916-921-6181	Fax	916-921-9213

Name (Print/Type)	Bernhard Kreten	Registration No. (Attorney/Agent)	27,037
Signature		Date	9/28/00

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# FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.  
Small Entity payments must be supported by a small entity statement,  
otherwise large entity fees must be paid. See Forms PTO/SB/09-12.  
See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT (\$ 504.00

## Complete If Known

Application Number  
Filing Date  
First Named Inventor Coelho, Philip H.  
Examiner Name  
Group / Art Unit  
Attorney Docket No. 30111-pa

### METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number 11-1734

Deposit Account Name Bernhard Kreten

☒ Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17

2. ☒ Payment Enclosed:

☒ Check ☐ Money Order ☐ Other

### FEE CALCULATION

#### 1. BASIC FILING FEE

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
101 690	201 345	Utility filing fee	345.
106 310	206 155	Design filing fee	
107 480	207 240	Plant filing fee	
108 690	208 345	Reissue filing fee	
114 150	214 75	Provisional filing fee	

SUBTOTAL (1) (\$ 345.

#### 2. EXTRA CLAIM FEES

Total Claims	Extra Claims	Fee from below	Fee Paid
29	-20** = 9	9	81.
5	-3** = 2	39.	78.
Multiple Dependent			

\*\*or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code	Small Entity Fee Code	Fee Description
103 18	203 9	Claims in excess of 20
102 78	202 39	Independent claims in excess of 3
104 260	204 130	Multiple dependent claim, if not paid
109 78	209 39	** Reissue Independent claims over original patent
110 18	210 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 159.

### FEE CALCULATION (continued)

#### 3. ADDITIONAL FEES

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath	
127 50	227 25	Surcharge - late provisional filing fee or cover sheet	
139 130	139 130	Non-English specification	
147 2,520	147 2,520	For filing a request for reexamination	
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	
115 110	215 55	Extension for reply within first month	
116 380	216 190	Extension for reply within second month	
117 870	217 435	Extension for reply within third month	
118 1,360	218 680	Extension for reply within fourth month	
128 1,850	228 925	Extension for reply within fifth month	
119 300	219 150	Notice of Appeal	
120 300	220 150	Filing a brief in support of an appeal	
121 260	221 130	Request for oral hearing	
138 1,510	138 1,510	Petition to institute a public use proceeding	
140 110	240 55	Petition to revive - unavoidable	
141 1,210	241 605	Petition to revive - unintentional	
142 1,210	242 605	Utility issue fee (or reissue)	
143 430	243 215	Design issue fee	
144 580	244 290	Plant issue fee	
122 130	122 130	Petitions to the Commissioner	
123 50	123 50	Petitions related to provisional applications	
126 240	126 240	Submission of Information Disclosure Stmt	
581 40	581 40	Recording each patent assignment per property (times number of properties)	
146 690	246 345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149 690	249 345	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify)

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 0.

### SUBMITTED BY

Name (Print/Type) Bernhard Kreten

Signature

Registration No. 27,037  
(Attorney/Agent)

### Complete (if applicable)

Telephone (916) 921-6181

Date 9/28/00

### WARNING:

Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10**

**Applicant:** Philip Henry Coelho and Pablo Rubinstein

**For:** Freezing and Thawing Bag, Mold, Apparatus and Method

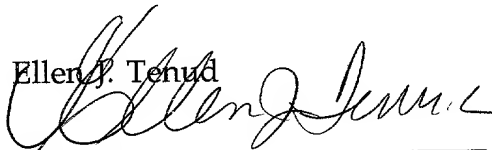
**Paper:**

1. A Patent Application (Utility) (comprised of pages 1 through 19) (copy from a prior application);
2. A Utility Patent Application Transmittal;
3. A Fee Transmittal (original and one copy);
4. A Declaration for Patent Application (copy from a prior application);
5. A Verified Statement Claiming Small Entity Status (Independent Inventor); (copy from a prior application)
6. Ten (10) sheets of drawing figures (comprised of figures 1 through 15);
7. A Preliminary Amendment;
8. A Letter to the Draftsman;
9. Six (6) sheets of formal drawing figures (comprised of figures 1 through 15);
10. A Form PTO-1449 (including prior art copies); and
11. A check in the amount of \$504.00, \$345.00 of which reflects the government filing fee for utility patent, \$81.00 of which is to cover the government fee for nine (9) claims in excess of twenty, and \$78.00 of which is to cover the government fee for two (2) independent claims in excess of three.

I hereby certify that the above identified correspondence, which is attached, is being deposited with the **United States Postal Service, Express Mail, Post Office to Addressee, mailing label #EK241513481US**, in an envelope addressed to:

Assistant Commissioner for Patents  
Box Patent Application  
Washington, D.C. 20231

on September 28, 2000.

Ellen J. Tenud  
  
(Signature)  
September 28, 2000  
(Date of Signature)

Applicant or Patentee: Philip Henry Coelho and Pablo RubinsteinSerial or Patent No.: \_\_\_\_\_ Attorney's Docket No.: 26097-paFiled or Issued: HerewithFor: Freezing and Thawing Bag, Mold, Apparatus and Method

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark described in:

XXX the specification filed herewith.

\_\_\_\_\_ application serial no.: \_\_\_\_\_, filed \_\_\_\_\_,  
\_\_\_\_\_ patent no.: \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign grant, convey or license any rights in the invention is listed below:

\_\_\_\_\_ no such person, concern, or organization.

XXX person, concerns or organizations listed below\*

\*NOTE: Separate verified statements are required for each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

FULL NAME ThermoGenesis Corporation

ADDRESS 2893 Sunrise Boulevard, Suite 206, Rancho Cordova, California 95742

☐ individual ☒ small business concern ☐ nonprofit organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon or any patent to which this verified statement is directed.

Philip Henry Coelho

Pablo Rubinstein

NAME OF INVENTOR

NAME OF INVENTOR

NAME OF INVENTOR

Signature of Inventor

Signature of Inventor

Signature of Inventor

Date

Date

Date

UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Coelho, et al.  
FOR: Freezing and Thawing  
Bag, Mold, Apparatus  
And Method

To: Commissioner of Patents and Trademarks  
Washington, DC 20231

PRELIMINARY AMENDMENT

Sir:

Before a First Office Action on the merits, kindly enter the following amendments:

IN THE SPECIFICATION

Page 1, line 4, kindly insert the paragraph – This application is a division of application number 08/978,171, filed November 25, 1997, status: pending, which is a division of application number 08/670,368, filed June 25, 1996, status: pending. – after “Freezing and Thawing Bag, Mold, Apparatus and Method”.

Page 11, line 4, kindly change “to” to -- two --.

IN THE ABSTRACT

Page 19, line 10, kindly delete “,” after -- placed --.

Page 19, line 10, kindly delete “,” after -- surfaces --.

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### IN THE CLAIMS

Kindly cancel claims 6 through 10, 14 through 18, 24 through 27, and 33 through 44 without prejudice or disclaimer as to their content.

#### Kindly Modify the Claims as Follows:

Claim 11, line 1, kindly insert -- formed -- after "is".

Claim 31, line 1, kindly change "method" to -- bag --.

Claim 32, line 1, kindly change "method" to -- bag --.

#### Kindly Amend the Claims as Follows:

Claim 1 (amended) - A breakage resistant medical freezing bag containing liquid, comprising, in combination:

a first bag portion formed from a blank of plastic sheet material having the ability to be deformed during bag fabrication; and subsequently retain a shape after fabrication having the following characteristics: a substantially planar outer wall, a radiused edge wall circumscribing said planar outer wall and peripheral flashing circumscribing said radiused edge wall,

a second bag portion sealed to said peripheral flashing and overlying said planar outer wall of said first bag portion, said first and second bag portions collectively defining a hollow enclosed volume to receive the liquid, [such that] said planar outer wall is spaced from said second bag portion by a dimension [at least] substantially equal to a radius of said radiused edge wall, said radiused edge wall dissipating forces engendered during phase change of the liquid in the bag during freezing and thawing and the liquid contained within said enclosed volume does not create sufficient hydrostatic force to appreciably change parallelism existing between said planar outer wall and said second bag portion.

Claim 19 (amended) - A method for forming a bag, the steps including:

forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold, and retaining its conformation, including a planar surface, radiused periphery and peripheral ledge,

removing the conformed sheet from the mold, and [enclosing the bag.]

closing the recess formed in the sheet with another sheet parallel to the planar surface.

Claim 28 (amended) - A breakage resistant medical bag formed by:

deforming a first sheet of pressure and/or thermosetting material which has a memory to retain its deformed state to maintain [have] a planar outer wall, a radiused edge wall circumscribing said outer wall and peripheral flashing circumscribing said edge wall oriented parallel to said outer wall and defining a pocket,

sealing the pocket with a second sheet of material including a wall parallel to said planar outer wall,

said bag thereby defining a contoured, enclosed volume which receives a liquid therein constrained to conform to said contoured enclosed volume by virtue of said memory and by said radiused edge wall.

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**Kindly Add the New Claims as Follows:**

Claim 46 - A vacuum forming bag mold, comprising, in combination:  
a planar surface;  
a peripheral support to receive a sheet material blank thereon and said support spaced from and parallel to said planar surface connected by a wall; and  
at least one relief area defining an access fluid receiving portal projecting from said wall.

Claim 47 - The bag mold of claim 46 wherein said wall has a slope which changes along its entire extent when viewed in cross-section extending from said planar surface to said peripheral support.

Claim 48 - The bag mold of claim 47 including at least one partition extending perpendicularly from said planar surface and dividing the mold into at least two compartments.

Claim 49 - The bag mold of claim 48 including an access passageway between each said compartment and passing through each said partition.

Claim 50 - The bag mold of claim 49 wherein said access passageway includes two channels per partition, one remote from the other.

Claim 51 - The bag mold of claim 50 wherein the compartments are not of equal size.

Claim 52 - The bag mold of claim 51 wherein a larger compartment includes at least two relief areas defining access portals.

Claim 53 - The bag mold of claim 52 wherein a smaller compartment includes at least one relief area defining an access portal.



Claim 54 - The bag mold of claim 53 further comprising means for conforming said sheet material blank of pressure and/or temperature sensitive material to a contour of the mold and retain the contour.

Claim 55 - The bag mold of claim 54 wherein said sheet material is comprised of a plastic material.

**REMARKS**

This Preliminary Amendment is provided before receipt of any substantive Office Action on the merits in this case and is provided to rectify various minor typographical inexactitudes and to present amended and new claims for the Examiner's kind consideration. No new matter has been presented.

In view of the foregoing, it is respectfully requested that the Examiner enter these amendments to this case.

Dated: September 28, 2000

Respectfully Submitted:

  
BERNHARD KRETEN

Applicant's Attorney

Telephone (916) 921-6181

Registration No.: 27,037

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TITLE OF THE INVENTION

Freezing and Thawing Bag, Mold, Apparatus & Method

2009/04/23/2009

## FIELD OF THE INVENTION

The following invention relates to an apparatus for forming flexible bags, a method for forming the flexible bag and the bag itself. More specifically, the following invention relates to bags to contain thermolabile and/or cellular biological substances and formed such that they can withstand stresses at extremely cold, cryogenic temperatures, reduce heat invasion from a higher ambient temperature into a plurality of such bags placed together, reduce storage space required for a plurality of such bags, and provide a thin and substantially constant cross-section for the bag so that the rate of heat transfer into and out of the bag is substantially homogenous throughout the contents of the bag thereby providing an improved means of protecting the viability of living cells during freezing and thawing.

## BACKGROUND OF THE INVENTION

Preservation of blood, cellular biological substances, tissue and other thermolabile products frequently involves product maintenance at extremely cold temperatures. Cellular biological substances are the fundamental, structural and functional unit of living organisms. Thermolabile substances are those substances which are easily altered or decomposed by heat. One economical mode for containment involves the use of encapsulating plastic since plastic is relatively inexpensive and lends itself to mass production techniques. However, many plastics suffer from brittleness at extremely low cryogenic temperatures and seams are sometimes susceptible to fracture.

In addition, bags that are formed either by folding over a planar material and seaming along peripheries or layering two planar materials and seaming along the peripheries have a generally ovoid shape when filled with a liquid. This is because the cross-sectional area adjacent either the fold or the seam has an area of decreasing cross-sectional width as it tapers from the center. While for many applications, this type of narrowing is unobjectionable, for certain biological fluids such as white stem cells, a bag having non-uniform thickness along its cross-section may impair the integrity of the biological product, particularly during temperature changes. One reason for quality loss during a change in temperature may involve the differential thermal gradient within the thermolabile or cellular substance caused by variations in thickness induced by the geometric shape of the bag itself. Stated alternatively, the center portion of the bag is thicker than the edges.

A corollary to the above-enunciated problem entails the fact that the prior art bags, with their thicker center portions, also provides a non-planar surface on opposing sides of the bag. This results in a "high spot" which also makes uniform temperature alteration of the contents difficult especially when heat exchange is attempted by contact with a substantially planar surface that provides the heat gradient. Because the bag has

a high area, uniform contact along the entire cross-section of the surface will have been precluded.

Figure 8 reflects prior art bag structure and highlights the inherent problems associated therewith. The radio frequency seam S is thinner than the non-seamed plastic forming the bag and has its weakest point W at an edge of the seal closest to the interior I. When the product P begins to freeze, the product freezes first at the thinnest part of the bag, i.e. at edge E. Freezing proceeds inwardly, from the outside in, until an unfrozen core C exists. As the core C freezes, it expands and generates forces F which collimate and focus on the edge E because of the geometrical configuration of the bag. The force F frequently causes bag rupture at the weakest point W because the wedging force appearing at edge E tries to separate the seam with a turning moment M. Recall the bag material tends to become brittle at low temperatures, exacerbating this problem.

Figure 13 reveals a further site of prior art bag weakness. When an access port tube T is to be fitted to the bag, two horseshoe-shaped RF horns H close on the plastic membrane around the tube T and then the membrane at the seal area S. This causes another weakened area W where bag failures commonly occur.

## SUMMARY OF THE INVENTION

The instant invention addresses all of the difficulties noted hereinabove. One manifestation of the problems solved includes the formation of peripheral seams circumscribing the bag which are appreciably stronger than prior art seam structures. Preferably, the bag is formed from two symmetrical sections, each vacuum formed to provide a major wall flanked by a radiused end wall section and circumscribed by a peripheral flange. It is contemplated in one form of the invention that two half portions defining a plane of symmetry are thus formed and adhered together so that the peripheral flanges are in mating registry and sealed such as by means of adhesive, ultrasonic, R.F. welding or other means. The increased surface area of the peripheral seam flange coupled with the radiused end wall interposed between the seam flange and the major wall of the bag dissipate forces which in prior art bags could have lent themselves to rupture at the seam area.

By vacuum forming the two halves, the contour of the side wall can be carefully controlled to make them substantially planar. Thus, when the two halves are united, a container having substantially uniform cross-section substantially along the entire extent will have been provided. This geometry encourages uniform thawing, freezing and imperviousness to the stresses that attend the seams and the radiused end wall at cryogenic temperatures. This geometry also provides space efficient storage and reduced heat invasion from a warmer ambient medium when the plurality of bags are placed with their planar surfaces in contact with each other.

## OBJECTS OF THE INVENTION

Accordingly, it is an object of the present invention to provide a useful and novel bag for containing thermolabile or live cell products, a method for making same and an apparatus associated with the formation of the bag.

A further object of the present invention is to provide a device as characterized above in which the seams associated therewith have greater strength to improve the integrity of the bag.

A further object of the present invention is to provide a device as characterized above in which the major surfaces of the bag are closely spaced, parallel and substantially planar thereby increasing the likelihood that heat transfer along those planar surfaces will more uniformly alter the temperature profile of the contents within the bag.

A further object of the present invention is to provide a device as characterized above which lends itself to mass production techniques, is extremely safe to use and is durable in construction.

A further object of the present invention is to provide a device as characterized above which is substantially rectangular so as to allow the device to be stacked side by side and end to end with minimal wasted space thereby achieving space efficient storage at low temperatures which results in a reduced operating cost.

A further object of the present invention is to provide a device as characterized above which has two parallel planar surfaces which make up a high percentage of the total exterior surface of the container such that when two or more such containers, lowered to subzero temperatures, are placed in contact with each other along these large planar surfaces, the percentage of the total surface area of the combined containers available to absorb heat from a surrounding warmer medium is substantially reduced.

Viewed from a first vantage point, it is an object of the present invention to provide a bag comprising, in combination: a first bag portion having a substantially planar outer wall, a radiused edge wall circumscribing the planar outer wall and

peripheral flashing circumscribing the radiused edge wall, a second bag portion sealed to the peripheral flashing and overlying the planar outer wall of the first bag portion such that the planar outer wall is spaced from the second bag portion by a dimension at least equal to a radius of the radiused edge wall.

Viewed from a second vantage point, it is an object of the present invention to provide a method for forming a bag, the steps including: forming a first mold having a recess including a planar surface, a radiused periphery circumscribing the planar surface and a peripheral ledge circumscribing the radiused periphery and oriented parallel to the planar surface, placing a blank of sheet material over the first mold, and causing the blank to conform to the mold, removing the formed sheet and enclosing the bag.

Viewed from a third vantage point, it is an object of the present invention to provide a bag formed by: deforming a first sheet of material to have a planar outer wall, a radiused edge wall circumscribing the outer wall and peripheral flashing circumscribing the edge wall oriented parallel to the outer wall and defining a pocket, sealing the pocket with a second sheet of material.

Viewed from a fourth vantage point, it is an object of the present invention to provide a mold for forming bags comprising, in combination: a recess including a planar surface, a radiused periphery circumscribing the planar surface and a peripheral ledge circumscribing the radiused periphery and oriented parallel to the planar surface, means for receiving a blank of sheet material over the recess and lapped atop the peripheral ledge, and means for conforming the sheet material blank to a contour of the mold.

These and other objects will be made manifest when considering the following detailed specification when taken in conjunction with the appended drawing figures.



## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a female mold according to the present invention.

Figure 2 is a side view of one type of bag that can be formed from the mold of figure 1.

Figure 3 is a perspective view of figure 2.

Figure 4 is an end view of figure 2.

Figure 5 is an alternate to figure 4.

Figures 6(A-C) are perspective views of a first bag portion (6A), a second bag portion (6B) and the two portions placed in mating registry (6C).

Figure 7 is a perspective view of a mold plug.

Figure 8 reflects prior art bag structure and forces generated in prior art bags.

Figure 9 is a perspective view of an alternative to figures 2 through 5.

Figure 10 is a front view of figure 9.

Figure 11 is a top view of figure 10.

Figure 12 is an end view of figure 10.

Figure 13 reflects prior art technology in anchoring a port tube into a figure 8 type prior art bag.

Figure 14 reflects sealing structure and methodology for a port tube communicating through the bag according to one form of the present invention.

Figure 15 depicts the improvement over figure 8.

## DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to the drawings, wherein like reference numerals denote like parts throughout the various drawing figures, reference numeral 10 is directed to the bag according to the present invention.

In its essence, the bag is formed from a first half and a second half. Preferably each half includes a planar outer wall and a peripherally disposed radiused edge wall that terminates in peripheral flashing, the flashing oriented parallel to and spaced from the planar outer wall by the dimension of the radius. In a preferred form, each half forming the bag is a symmetrical mirror image of the other so that the overall thickness of the bag is twice the radius of either half. In another form of the invention, however, the bag can be formed as having a first half as above-described and a second half as a planar back wall overlying a recess formed by the first half and adhered to the first half by the peripheral flashing.

More particularly, the bag as shown in figures 2 through 4 include a planar outer wall 2 which terminates in a peripherally disposed edge wall 4 having a constant radius of curvature and terminating in a peripheral flashing 6 oriented substantially parallel to the planar outer wall 2. Thus, the peripheral flashing 6 is spaced from the planar outer wall 2 by the radius defining the radiused edge wall 4 and defining the recess therein.

Figure 2 further reflects an inlet tube 121 formed with a series of necked-down constrictions 123 along its length. This tube 121 can store samples of the contents of the bag 10 where each sample 125a, 125b, 125c, etc. can be sequestered from adjacent samples by sealing at the nearest constriction 123.

Figure 5 shows the version where the second half is formed from a planar sheet 8 with the first half as described for figures 2 through 4. In all embodiments, access is provided to an interior of the bag by way of at least one portal 12.

Figure 2 and figure 3 each show three portals 12 allowing communication with the interior of the bag 10. The portal is formed concurrently with the first and second

halves when the embodiment of figures 2 through 4 are to be made. The portal 12 will appear on only one half of the bag in the figure 5 embodiment. Figure 2 and figure 3 also reflect a sealed area 14 which defines an area of demarcation between a first compartment 16 and a second compartment 18 for the bag 10. Although illustrative, other compartments could be provided. The compartments 16 and 18 can be placed in fluid communication by means of a passageway 20 extending at both an upper and lower extremity of the sealed portion 14. Each passageway 20 can be subsequently heat sealed.

Typically, once the bag has been filled, the bag is massaged to urge the contents into both compartments 16 and 18. Further, the bag is manipulated to assure the segments in areas 125a, 125b, 125c, etc. are filled. Then a heat sealer can close passageways 20 (at 21) and at each constriction 123. This is desirable because once the bag is stored at cryogenic temperatures, it is preferred to minimize temperature spikes. Accordingly, a cutout 15 can appear along a central portion of sealed portion 14 so that a minimum amount of time is required to sever compartment 18 from 16. Conversely, no compartments are also contemplated as part of the invention. Please see the bag 10' of figures 9 through 12 where like parts share like numerals.

Figure 1 reflects a complementally formed female mold for allowing one half of the bag to be formed. As shown in figure 1, the female mold 30 includes a contour complementary to the bag so that the bag is a true reflection of the mold. More specifically, the planar outer wall 2 of bag 10 has its corresponding part in mold 30 as planar surface 32. Similarly, the radiused edge wall 4 of bag 10 finds its counterpart with radiused edge wall 34. Likewise, the peripheral flashing 6 finds its counterpart at the flashing support 36. In like manner, the access portals 12 are formed by portal recesses 42.

Figure 6(A-C) shows first and second bag portion halves (6A, B, respectively) and assemblage (6C) of the two halves. Alternatively, figures 6A and 6B could illustrate male mold halves over which planar blanks of plastic are draped and then deformed,

for example, under heat and/or pressure. In such a case, the outer wall 2 of the bag portions are formed by mold wall 72. Radiused edge 4 is formed with edge 74. Access portals 12 are formed via projections 82. Partition 14 finds its counterpart in mold form 84 forming to compartments defined by 86 and 88.

Figure 14 reflects structure and methodology for placing a port tube 90 into a portal 12, as shown in figure 6C. One peripheral flange 6 is sealed to the other using a complementary RF die 101 which circumscribes the compartment(s) 16 (18, etc.). Where the die 101 contacts the portal 12, the die has a corresponding arcuate portion 103. Because the plastic which formed the portal was deformed as set forth in figure 1 (or 6), the plastic has uniform thickness throughout and particularly regarding the correct tubular shape. This results in a thicker and stronger sealing - joining area, especially as compared with figure 13. As the plastic is heated and cooled both during fabrication and use, it will have been stress relieved.

Figure 7 shows a plug 57 to be received with the port tube 90 and with portal 12. The preform 57 comprises an inner first rod 53 and second concentric cylinder 55, connected by an annular top wall 51. Central to annular top wall 51 is a bore 59 extending partially into rod 53. The outer cylinder 55 is shorter than the inner rod 53.

The passageway 20 (figure 2) that allows communication between a first compartment and a second compartment 18 includes a relief area defining passageway 40 (figure 1) so that the first compartment forming recess 46 can communicate with the second compartment forming recess 48. A partition 49 constitutes the zone of demarcation between the adjacent compartments.

In fabrication, a sheet of plastic material overlies the mold 30 and the planar material is forced within the contour defined by the mold 30. This can be done by positive pressure on the side of the sheet of material opposite from the mold or it can be formed by vents V forming a vacuum within the mold cavity to draw the plastic down. The forming process can be coupled with heat and pressure and the plastics can

be formed from a family of plastics characterized by their ability to deform and retain in memory their deformed state caused by the application of heat and or pressure.

Where the figure 5 bag is to be used, a substantially planar blank of plastic is placed in overlying registry with respect to the one preformed half defined by one planar outer wall, radiused edge wall and peripheral flashing and is adhered thereto by means of adhesive, ultrasonic welding or other fastening techniques.

Preferably, however, a second mold having mirror symmetry to the figure 1 mold (as in figures 6A, B) allows a second half to be formed which is the mirror image of the first half. Thus, the peripheral flange defined by the peripheral flashing 6 is placed in overlying registry, aligning both halves (as shown in figure 6C) and then a welding technique can be used as mentioned above.

The radiused edge wall includes the advantages illustrated in figure 15. First, the planar outer wall does not have any high spots and therefore presents a substantially uniform thickness along the entire length of the bag. In addition, the radiused edge wall minimizes the existence of stress areas by dissipating focusing forces so that failure of the bag at the seam site will have been made much less likely. Finally, the peripheral flashing provides an improved purchase area for causing two halves of the bag to be united since there is an abundance of material easily accessible for adherence either by an adhesive or by welding technology.

Having thus described the invention, it should be apparent that numerous structural modifications and adaptations may be resorted to without departing from the scope and fair meaning of the instant invention as set forth hereinabove and as described hereinbelow by the claims.

## CLAIMS

I Claim:

Claim 1 - A bag comprising, in combination:

a first bag portion having a substantially planar outer wall, a radiused edge wall circumscribing said planar outer wall and peripheral flashing circumscribing said radiused edge wall,

a second bag portion sealed to said peripheral flashing and overlying said planar outer wall of said first bag portion such that said planar outer wall is spaced from said second bag portion by a dimension at least equal to a radius of said radiused edge wall.

Claim 2 - The bag of claim 1 wherein said bag contains thermolabile substances.

Claim 3 - The bag of claim 1 wherein said bag contains cellular biological substances.

Claim 4 - The bag of claim 1 wherein an interior of said bag communicates with an exterior by means of a portal.

Claim 5 - The bag of claim 4 wherein said portal extends through said flashing.

Claim 6 - The bag of claim 5 wherein a partition is provided within said bag defining an area of demarcation in said bag including at least two compartments separated one from the other by said partition.

Claim 7 - The bag of claim 6 wherein a second portal is provided such that one portal communicates with said first compartment and another portal communicates with said second compartment.

Claim 8 - The bag of claim 7 wherein said compartments communicate with each other by a passageway.

Claim 9 - The bag of claim 8 wherein said passageway includes means to prevent through communication therebetween.

Claim 10 - The bag of claim 9 wherein said bag second portion is symmetrical to said first portion.

Claim 11 - The bag of claim 1 wherein said bag second portion is symmetrical to said first portion.

Claim 12 - The bag of claim 11 wherein an interior of said bag communicates with an exterior by means of a portal.

Claim 13 - The bag of claim 12 wherein said portal extends through said flashing.

Claim 14 - The bag of claim 13 wherein a partition is provided within said bag defining an area of demarcation in said bag including at least two compartments separated one from the other by said partition.

Claim 15 - The bag of claim 14 wherein a second portal is provided such that one portal communicates with said first compartment and another portal communicates with said second compartment.

Claim 16 - The bag of claim 15 wherein said compartments communicate with each other by a passageway.

Claim 17 - The bag of claim 16 wherein said passageway includes means to prevent through communication therebetween.

Claim 18 - The bag of claim 17 wherein said passageway has walls formed from material which can be fused to provide sealing.

Claim 19 - A method for forming a bag, the steps including:

forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold,

removing the formed sheet and enclosing the bag.

Claim 20 - The method of claim 19 including containing within said bag thermolabile substances.

Claim 21 - The method of claim 19 including containing within said bag cellular biological substances.

Claim 22 - The method of claim 19 wherein enclosing the bag is performed by forming a second mold having a mirror image of the first mold and placing a blank of sheet material over said second mold causing the blank to conform to the mold and forming the bag by registering the formed sheet from the first mold and formed sheet from the second mold together.

Claim 23 - The method of claim 22 including forming a plurality of portals passing into an interior of the bag by providing a portal shaped recess on both the first mold and the second mold.

Claim 24 - The method of claim 23 including providing a partition in the mold so that at least two compartments are defined within the mold so that each formed sheet when united will define two compartments in the bag.

Claim 25 - The method of claim 24 including providing a passageway between the two compartments by providing an access in the mold adjacent the partition, bridging the partition and allowing communication between the first and second compartment.

Claim 26 - The method of claim 25 including providing portals for all compartments.

Claim 27 - The method of claim 26 including sealing the peripheral flashing of each formed sheet by adhering the peripheral flashing causing molecular excursions between the two formed sheets.

Claim 28 - A bag formed by:

deforming a first sheet of material to have a planar outer wall, a radiused edge wall circumscribing said outer wall and peripheral flashing circumscribing said edge wall oriented parallel to said outer wall and defining a pocket,



sealing the pocket with a second sheet of material.

Claim 29 - The bag of claim 28 wherein said bag contains thermolabile substances.

Claim 30 - The bag of claim 28 wherein said bag contains cellular biological substances.

Claim 31 - The method of claim 28 wherein enclosing the bag is performed by forming a second mold having a mirror image of the first mold and placing a blank of sheet material over said second mold causing the blank to conform to the mold and forming the bag by registering the formed sheet from the first mold and formed sheet from the second mold together.

Claim 32 - The method of claim 31 including forming a plurality of portals passing into an interior of the bag by providing a portal shaped recess on both the first mold and the second mold.

Claim 33 - The method of claim 32 including providing a partition in the mold so that at least two compartments are defined within the mold so that each formed sheet when united will define two compartments in the bag.

Claim 34 - The method of claim 33 including providing a passageway between the two compartments by providing an access in the mold adjacent the partition, bridging the partition and allowing communication between the first and second compartment.

Claim 35 - The method of claim 34 including providing portals for all compartments.

Claim 36 - The method of claim 35 including sealing the peripheral flashing of each formed sheet by adhering the peripheral flashing causing molecular excursions between the two formed sheets.

Claim 37 - A mold for forming bags comprising, in combination:

a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface,

means for receiving a blank of sheet material over said recess and lapped atop said peripheral ledge, and

means for conforming the sheet material blank to a contour of the mold.

Claim 38 - The mold of claim 37 including a relief area to define an access portal into the mold cavity for providing a portal into the formed bag.

Claim 39 - The mold of claim 38 including a partition interposed within a portion of the mold dividing the mold into at least two compartments.

Claim 40 - The mold of claim 39 including providing an access passageway between the first and second compartments and passing through the partition.

Claim 41 - The mold of claim 40 including a portal located addressing each of the compartments.

Claim 42 - The mold of claim 41 including a second mold having a mirror symmetry with the first mold so that the bag formed thereby has a thickness twice the radius of one mold.

Claim 43 - The mold of claim 42 wherein the formed bag contains thermolabile substances.

Claim 44 - The mold of claim 42 wherein the formed bag contains cellular biological substances.

Claim 45 - A method of reducing breakage in plastic containers made from two plastic co-planar sheets sealed at the periphery and into which access ports are incorporated comprising:

vacuum forming a shape into each of the co-planar sheets such that a recess is formed defined by a planar wall, and

[illegible]

## ABSTRACT OF THE DISCLOSURE

A bag, method of manufacture and process are disclosed for the cryopreservation of thermolabile substances. The bag is characterized as having substantially uniform thickness throughout its length and height. The bag features a radiused peripheral edge wall for stress relief and to provide the constant cross-section. A peripheral flashing circumscribes the radiused edge wall and provides a suitable purchase area for sealing so that the thus formed bag is less susceptible to fracture particularly when exposed to cryogenic temperatures. The uniform thickness of the bag promulgates uniform heat transfer to and from the contents of the bag in relation to any surrounding medium at a different temperature. The bag affords more space for efficient storage and reduces heat invasion into the contents of the bag when a plurality of bags are placed with their larger planar surfaces in contact with each other.





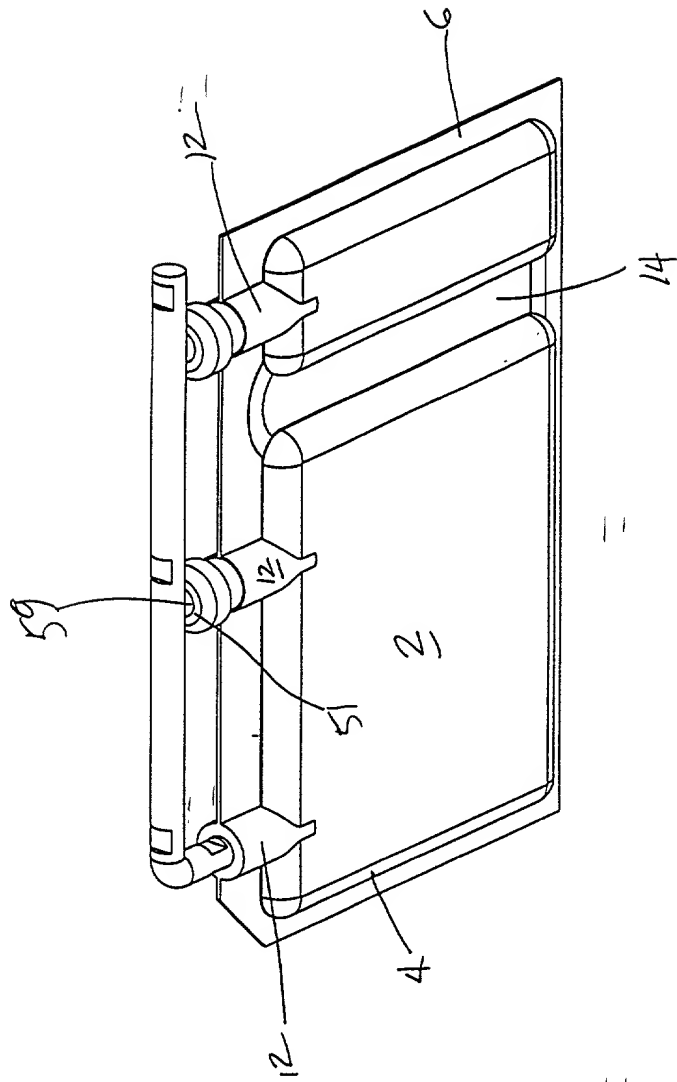


FIG 3

FIG 4

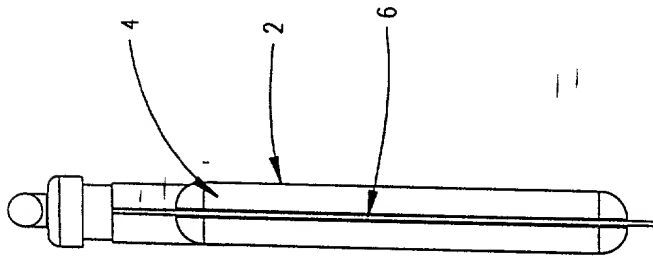
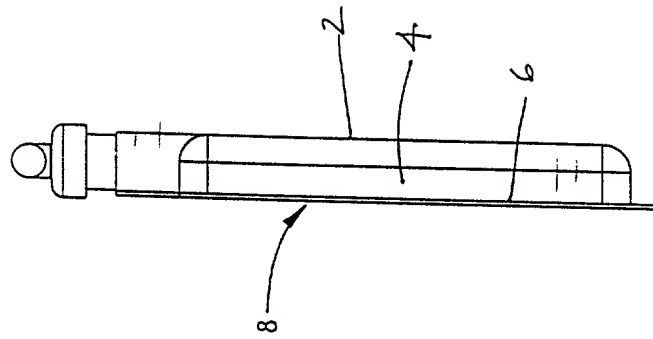


FIG 5





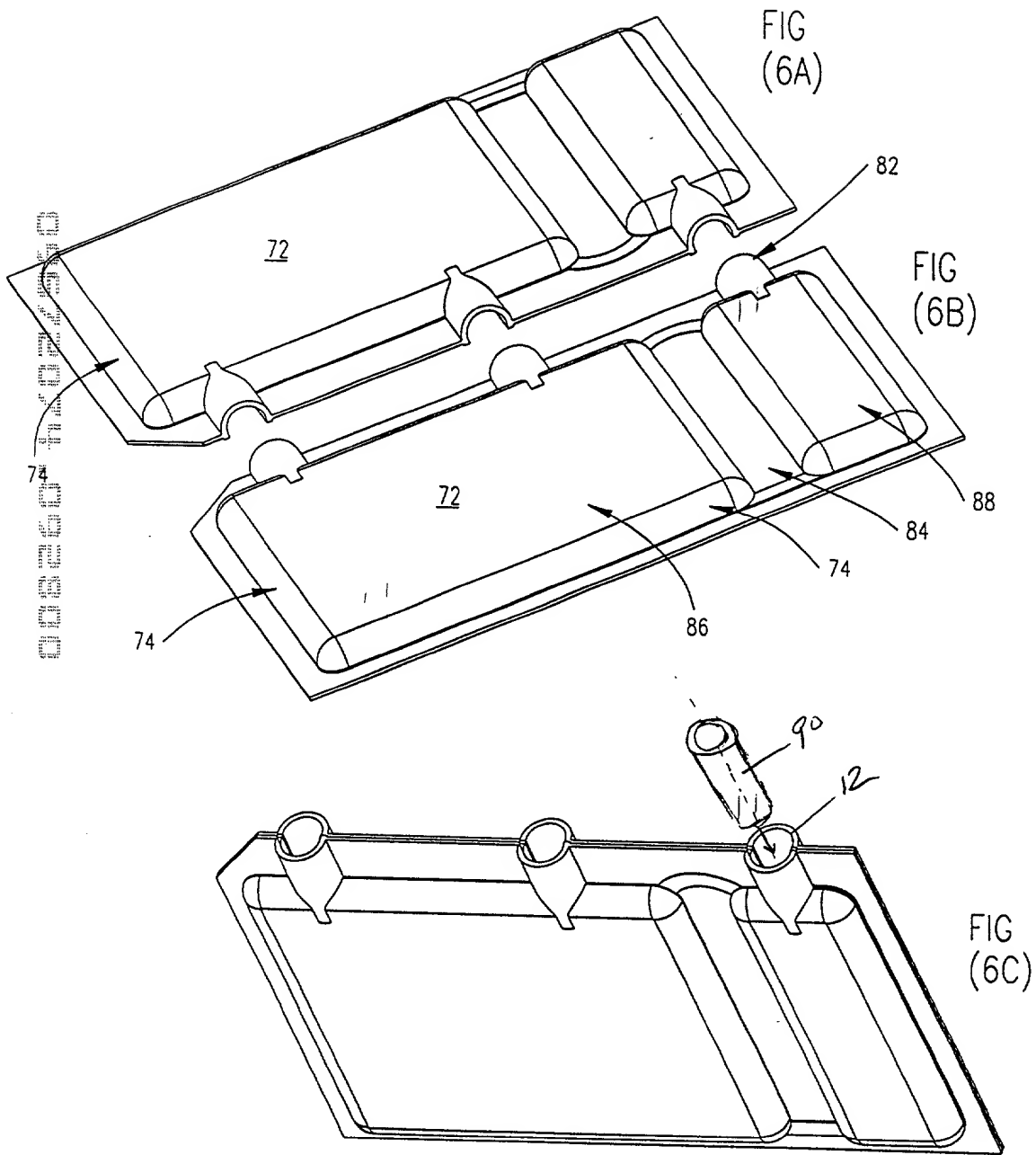
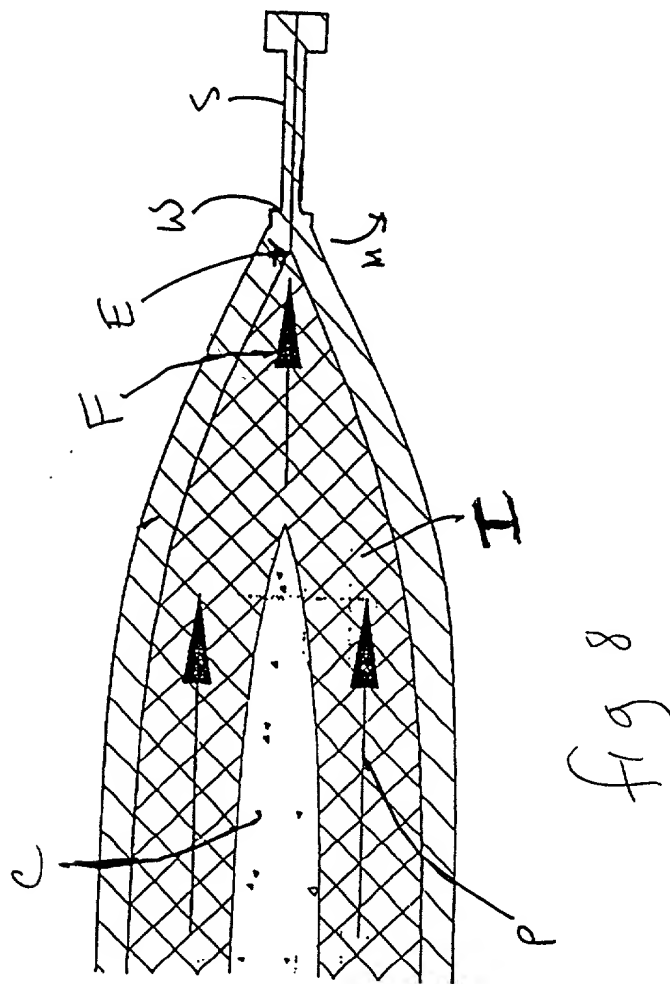


FIG 6



[illegible]

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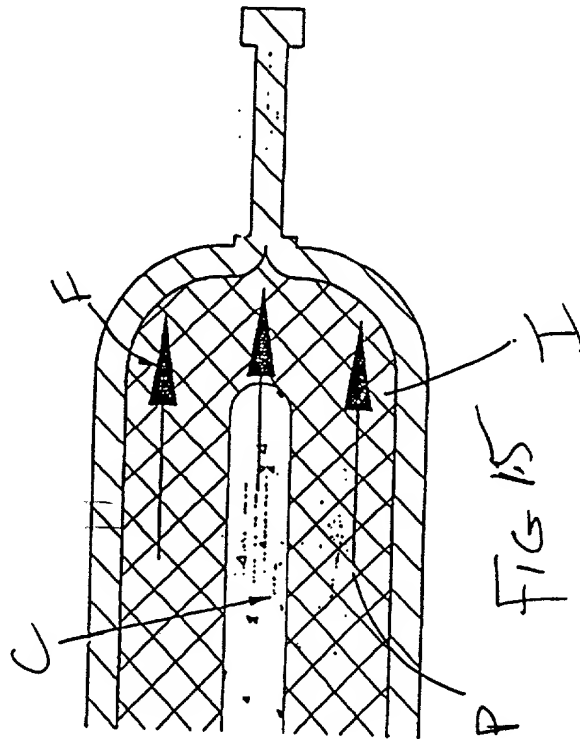
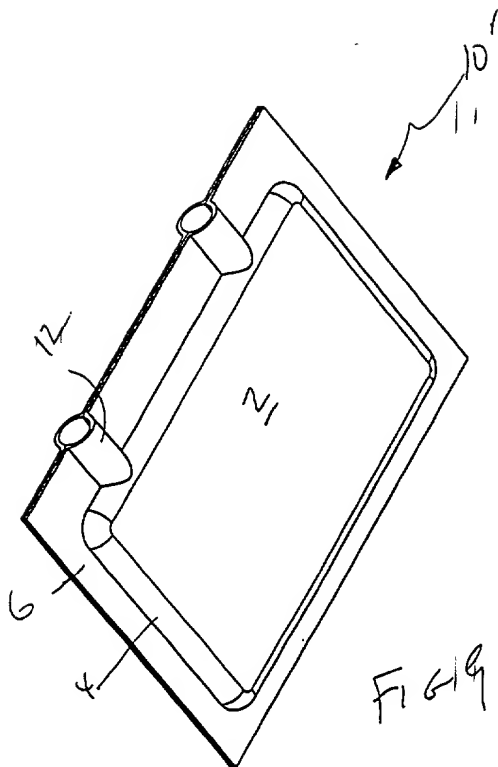


FIG 15-1

[illegible]

F1 G19

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Table 1. Demographic characteristics of the study population	
Age (years)	65.0 ± 10.0
Gender	
Male	50 (50.0%)
Female	50 (50.0%)
Education (years)	12.0 ± 2.0
Marital status	
Married	40 (80.0%)
Single	10 (20.0%)
Occupation	
Retired	30 (60.0%)
Unemployed	20 (40.0%)
Income (USD/month)	1000.0 ± 500.0
Health status	
Good	30 (60.0%)
Poor	20 (40.0%)
Comorbidities	
Hypertension	15 (30.0%)
Diabetes	10 (20.0%)
Cholesterol	12 (24.0%)
Smoking status	
Smoker	10 (20.0%)
Non-smoker	40 (80.0%)
Alcohol consumption	
Regular	5 (10.0%)
Occasional	15 (30.0%)
Never	30 (60.0%)

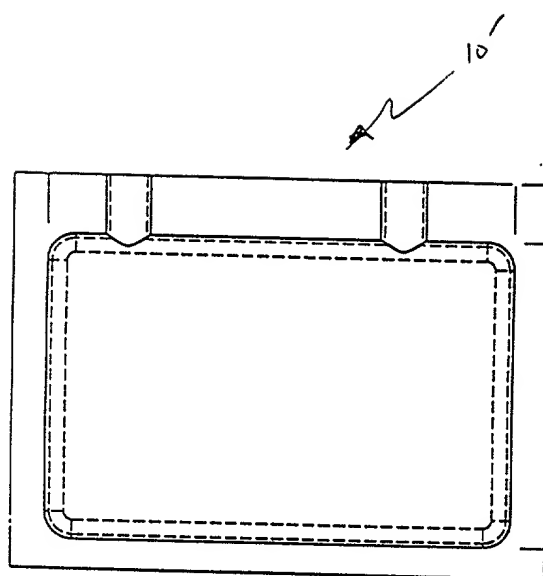


FIG 10

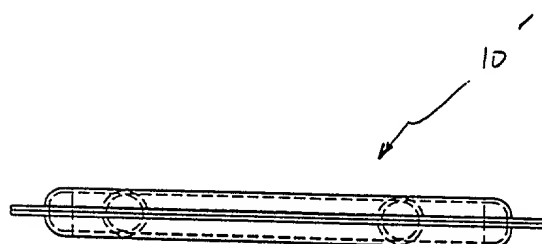
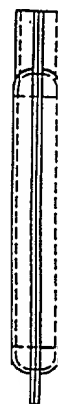
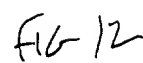
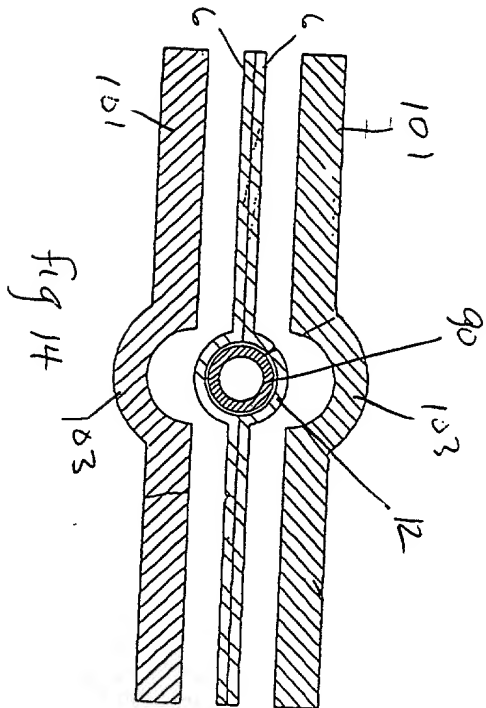
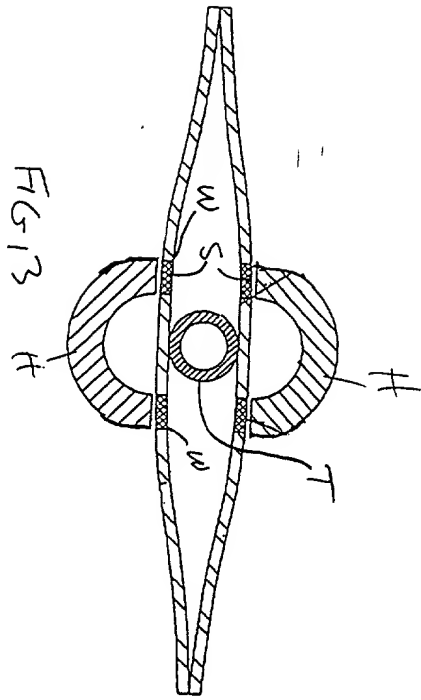


FIG 11





Parameter	Value	Unit
Initial concentration	0.1	mol/L
Temperature	25	°C
Time	0, 1, 2, 4, 8, 16, 32, 64, 128, 256, 512, 1024, 2048, 4096, 8192, 16384, 32768, 65536, 131072, 262144, 524288, 1048576, 2097152, 4194304, 8388608, 16777216, 33554432, 67108864, 134217728, 268435456, 536870912, 1073741824, 2147483648, 4294967296, 8589934592, 17179869184, 34359738368, 68719476736, 137438953472, 274877906944, 549755813888, 1099511627776, 2199023255552, 4398046511104, 8796093022208, 17592186044416, 35184372088832, 70368744177664, 140737488355328, 281474976710656, 562949953421312, 1125899906842624, 2251799813685248, 4503599627370496, 9007199254740992, 18014398509481984, 36028797018963968, 72057594037927936, 144115188075855872, 288230376151711744, 576460752303423488, 1152921504606846976, 2305843009213693952, 4611686018427387904, 9223372036854775808, 18446744073709551616, 36893488147419103232, 73786976294838206464, 147573952589676412928, 295147905179352825856, 590295810358705651712, 1180591620717411303424, 2361183241434822606848, 4722366482869645213696, 9444732965739290427392, 18889465931478580854784, 37778931862957161709568, 75557863725914323419136, 151115727451828646838272, 302231454903657293676544, 604462909807314587353088, 1208925819614629174706176, 2417851639229258349412352, 4835703278458516698824704, 9671406556917033397649408, 19342813113834066795298816, 38685626227668133590597632, 77371252455336267181195264, 154742504910672534362390528, 309485009821345068724781056, 618970019642690137449562112, 1237940039285380274899124224, 2475880078570760549798248448, 4951760157141521099596496896, 9903520314283042199192993792, 19807040628566084398385987584, 39614081257132168796771975168, 79228162514264337593543950336, 158456325028528675187087900672, 316912650057057350374175801344, 633825300114114700748351602688, 1267650600228229401496703205376, 2535301200456458802993406410752, 5070602400912917605986812821504, 10141204801825835211973625643008, 20282409603651670423947251286016, 40564819207303340847894502572032, 81129638414606681695789005144064, 162259276829213363391578010288128, 324518553658426726783156020576256, 649037107316853453566312041152512, 1298074214633706907132624082305024, 2596148429267413814265248164610048, 5192296858534827628530496329220096, 10384593717069655257060992658440192, 20769187434139310514121985316880384, 41538374868278621028243970633760768, 83076749736557242056487941267521536, 166153499473114484112975882535043072, 332306998946228968225951765070086144, 664613997892457936451903530140172288, 1329227995784915872903807060280344576, 2658455991569831745807614120560689152, 5316911983139663491615228241121378304, 10633823966279326983230456482242756608, 21267647932558653966460912964485513216, 42535295865117307932921825928971026432, 85070591730234615865843651857942052864, 170141183460469231731687303715884105728, 340282366920938463463374607431768211456, 680564733841876926926749214863536422912, 1361129467683753853853498429727072845824, 2722258935367507707706996859454145691648, 5444517870735015415413993718908291383296, 10889035741470030830827987437816582766592, 21778071482940061661655974875633165533184, 43556142965880123323311949751266331066368, 87112285931760246646623899502532662132736, 174224571863520493293247799005065324265472, 348449143727040986586495598010130648530944, 696898287454081973172991196020261297061888, 1393796574908163946345982392040522594123776, 2787593149816327892691964784081045188247552, 5575186299632655785383929568162090376495104, 11150372599265311570767859136324180752990208, 22300745198530623141535718272648361505980416, 44601490397061246283071436545296723011960832, 89202980794122492566142873090593446023921664, 178405961588244985132285746181186892047843328, 356811923176489970264571492362373784095686656, 713623846352979940529142984724747568191373312, 1427247692705959881058285969449495136382746624, 2854495385411919762116571938898990272765493248, 5708990770823839524233143877797980545530986496, 11417981541647679048466287755595961091061972992, 228359630832953580969325755111919221821239	

UNITED STATES PATENT AND TRADEMARK OFFICE

<b>APPLICANT:</b>	Coelho, et al.
<b>FOR:</b>	Freezing and Thawing Bag, Mold, Apparatus And Method

To: Commissioner of Patents and Trademarks  
Washington, DC 20231

**LETTER TO THE DRAFTSMAN**

Subject to the Examiner's approval, kindly enter the enclosed six (6) sheets of formal drawing figures (comprised of figures 1 through 15) in place of the drawing figures as originally filed in the above-identified case.

Dated: September 28, 2000

Respectfully Submitted:



BERNHARD KRETEN  
Applicant's Attorney  
Telephone (916) 921-6181  
Registration No.: 27,037

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Freezing and Thawing Bag, Mold, Apparatus and Method the specification of which:

XXX is attached hereto.

\_\_\_\_\_ was filed on \_\_\_\_\_ as Application Serial No.: \_\_\_\_\_  
and was amended on: \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, (Code of Federal Regulations 1.56(a)).

I hereby claim foreign priority benefits under Title 35, U.S. Code 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed  
NO

(Number) (Country) (Day/Month/Year)

I hereby claim the benefit under Title 35, U.S. Code 120 of any U.S. application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior U.S. application in the manner provided by the first paragraph of Title 35, U.S. Code 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, 1.56(a), which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.) (Filing Date) (Status-patented, pending, abandoned)

I hereby appoint BERNHARD KRETEN, Reg. No. 27,037; LEONARD BLOOM, Reg. No. 18,369; JAMES R. GAFFEY; Reg. No. 20,259; ROBERT M. GAMSON, Reg. No. 32,986; BRUCE L. LAMB, Reg. No. 17,859 to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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